K004013

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Implex *Nexgen®* Complete Knee Solution Augmentation Patella

Submitter Name:	Implex Corp.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	John Schalago
Phone Number:	(201) 818-1800
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Date Prepared:	December 21, 2000
Device Trade Name:	The Implex Nexgen Complete Knee Solution-Augmentation Patella
Device Common Name:	Patellar Components
Classification Number and Name:	21 CFR § 888.3560

Substantial Equivalence:

The term "substantial equivalence" as used in this e510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

Implex *Nexgen* Complete Knee Solution-Augmentation Patella (subject of this 510(k) Premarket Notification) is manufactured from ultra-high molecular weight polyethylene (UHMWPE), porous tantalum, and titanium alloy. The Augmentation Patella is offered in two sizes (medium, and large), each size is offered in two thicknesses.

510(k) Summary (Continued)

Indications for Use:

The Implex *Nexgen®* Complete Knee Solution – Augmentation Patella is intended as for use include:

1) noninflamatory degenerative joint disease including osteoarthritis or traumatic arthritis, 2) rheumatoid arthritis, 3) correction of functional deformity, 4) revision procedures where other treatments or devices have failed, 5) treatment of fractures that are unmanageable using other techniques, and 6) complications from a failed prosthesis.

This device is intended for use with bone cement and/or supplemental fixation by means of suture attachment. Supplemental suture attachment may be used in cases where additional device support can be obtained.

Device Technological Characteristics and Comparison to Predicate Device:

The device technological characteristics are not significantly affected by interfacing of modified Implex Augmentation Patella with Zimmer femoral components or the design and labeling change described herein.

Conclusion:

The Implex *Nexgen®* Complete Knee Solution – Augmentation Patella is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2001

Mr. John Schalago
Manager, Regulatory Affairs
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K004013
Trade Name: *Nexgen*® Complete Knee Solution - Augmentation Patella
Regulatory Class: II
Product Code: JWH
Dated: December 22, 2000
Received: December 27, 2000

Dear Mr. Schalago:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K004013

Device Name: The Implex *Nexgen®* Complete Knee Solution Augmentation Patella

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K004013

Prescription Use (Per 21 CFR 801.109) X OR... Over-The-Counter Use _____

(Optional Format 1-2-96)